EXHIBIT 1

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2008

Ms. Kendra Basler
Regulatory Affairs Associate
Abbott Vascular
Cardiac Therapies
3200 Lakeside Drive
Santa Clara, CA 95054-2807

Re: P070015
XIENCE™ V Everolimus Eluting Coronary Stent System
PROMUS™ Everolimus Eluting Coronary Stent System
Filed: June 1, 2007
Amended: July 5, September 4, November 8, and December 13, 2007; February 20, April 2, May 12, May 13, June 9, June 23, and June 26, 2008
Procode: NIQ

Dear Ms. Basler:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the XIENCE™ V Everolimus Eluting Coronary Stent System, which will also be distributed as the PROMUS™ Everolimus Eluting Coronary Stent System. This device is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to *de novo* native coronary artery lesions (length ≤ 28 mm) with reference vessel diameters of 2.5 mm to 4.25 mm. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the periodic report (often referred to as annual report) requirements outlined in the enclosure, you have agreed to provide the following data in a separate postapproval study report:

1. You should collect and report to the Agency on an annual basis clinical outcomes through 5 years post-procedure on at least 80% of patients enrolled (excluding those discontinued due to death) from SPIRIT FIRST, SPIRIT II, SPIRIT III, and SPIRIT IV. When appropriate or as requested by FDA, you should submit PMA supplements requesting approval to update your Instructions for Use (IFU) to include these data.

2. You should collect clinical data on the implantation of the PMA-approved, commercially-distributed XIENCE V product in the U.S. The trial should be statistically powered to evaluate the annual rates of stent thrombosis, and the rate of cardiac death plus myocardial infarction (MI) through five years in patients treated with the XIENCE V stent according to its labeled indications. These data are needed to evaluate whether the rate of stent thrombosis plateaus or increases over time, and to evaluate the impact of stent thrombosis on rates of cardiac death and MI. These data are also needed to evaluate the potential for rare adverse events related to the drug substance and/or drug carrier that could not be detected in your initial clinical trials. You should also collect additional data on clinical outcomes (including target lesion revascularization rates at 12 months post-implantation) associated with use of the XIENCE V 4.0 mm diameter stent to confirm the outcomes observed in the 4.0 mm Arm of the SPIRIT III trial.

   You have proposed collecting these data from at least 5000 patients enrolled in the XIENCE V USA Postmarket Registry. FDA agrees that the registry protocol submitted in Supplement 97 of your Investigational Device Exemption (IDE), G050050, with the planned modifications to the statistical analysis plan, is acceptable. Please provide progress reports at 6, 12, 18, and 24 months and annually thereafter through 5 years with data from your U.S. registry. When appropriate or as requested by FDA, you should submit PMA supplements requesting approval to update your IFU to include these data. Please note that if subsequent data analyses identify areas of significant off-label use, you should submit an IDE to conduct an appropriate study to evaluate the off-label use.

3. You should conduct or participate in a study that will develop clinical data to identify the optimal duration of dual antiplatelet therapy following percutaneous intervention with the XIENCE V drug-eluting stent.

   The issue of the optimal duration of dual antiplatelet therapy following PCI with drug-eluting stents (DES) remains a key question that has not been addressed by any clinical trials conducted to date on the Cordis Cypher DES, the Boston Scientific Taxus Express[2] DES, the Endeavor DES, or the XIENCE V DES. At the December 7 – 8, 2006 meeting of FDA's Circulatory System Devices Advisory Panel meeting on DES thrombosis, the Panel recommended that the labeling for all marketed DES include the then-current ACC/AHA/SCAI guidelines for dual anti-platelet therapy, which specified that patients should receive aspirin indefinitely and clopidogrel for a minimum of 3 or 6 months for the Cypher or Taxus stents, respectively, after implantation, with this duration extended to 12 months in patients who are at low risk for bleeding complications.

However, it is important to recognize that the current recommendation for an extended duration of clopidogrel use reflects a consensus opinion among experts within cardiovascular professional societies based on limited data, rather than on rigorous randomized clinical trials. Further, it is not clear that 12 months is the optimal maximum duration of a dual anti-platelet therapy. In fact, the ACC/AHA/SCAI guidelines were recently revised to specify that patients with low bleeding risks should receive clopidogrel for at least 12 months post-procedure. While extending the duration of clopidogrel use may decrease the risk of very late stent thrombosis events, this strategy may also result in an increased risk for major bleeding complications and involves lifestyle modifications, such as deferral of surgical and dental procedures that may affect a patient's health and overall quality of life. Finally, it is known that stent thrombosis can occur in some individuals despite the continued use of dual antiplatelet therapy. With these considerations in mind, it is imperative that the risks and benefits of continued clopidogrel use be evaluated to determine with greater precision the optimal duration of dual anti-platelet therapy to ensure that these patients receive the best care possible.

Based on the important public health impact of this information, as stated above, you should collect clinical data to identify the optimal duration of dual anti-platelet therapy following PCI with the XIENCE V stent. Such an evaluation should encompass a consecutively enrolled patient population or utilize an approach to enroll patients representative of the actual use of your commercialized product. You may wish to limit your investigation to the XIENCE V stent, or your study may involve pooling with other approved drug-eluting stents. You may also choose to collect these data in a manner that would satisfy, wholly or in part, condition #2 above. When appropriate or as requested by FDA, you should submit PMA supplements requesting approval to update your IFU to include these data. You should submit your proposed plan to address this issue within six months of the date of this letter.

As FDA views the investigation of the optimal duration of dual anti-platelet therapy as a DES class effect, we are requesting that manufacturers of other approved DES collect the same information.

4. You should comply with the commitments made in Amendment 11 related to the implementation of updated final product testing methodologies.

Expiration dating for this device has been established and approved at 12 months.

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made

to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

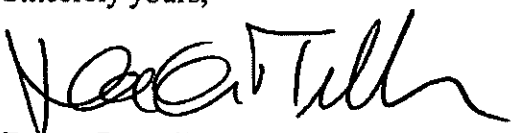
You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Dr. Heather Agler at 240-276-4229.

Sincerely yours,



Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

EXHIBIT 2

Abbott
A Promise for Life

Print This Page | Back to Web Page

Press Release

FDA Approves Abbott's XIENCE V™ Drug Eluting Stent

XIENCE V, Only Drug Eluting Stent to Demonstrate Superiority Over Market-Leading Stent in Clinical Trials, Now Available in United States for Treatment of Coronary Artery Disease

July 2, 2008

Abbott Park, Illinois (NYSE: ABT) — Abbott today announced that the U.S. Food and Drug Administration (FDA) approved the XIENCE V™ Everolimus Eluting Coronary Stent System for the treatment of coronary artery disease. XIENCE V is the only drug eluting stent to have demonstrated superiority over Boston Scientific's TAXUS® paclitaxel-eluting coronary stent system in two randomized head-to-head clinical trials. XIENCE V will be launched in the United States immediately.

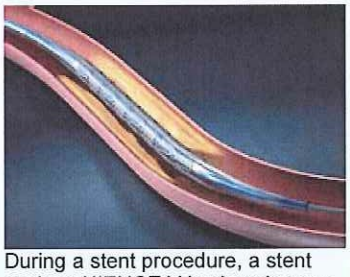
"XIENCE V represents an important treatment advance for the estimated 13 million people in the United States suffering from coronary artery disease, and we believe XIENCE V will quickly become the new standard for drug eluting stents given its outstanding clinical results," said John M. Capek, Ph.D., executive vice president, Medical Devices, Abbott. "Physicians in the United States have been waiting for years to treat their patients with a technology that delivers on the promise of drug eluting stents through both ease of use and excellent clinical performance, and XIENCE V is that technology."

The XIENCE V drug coated stent is used to treat coronary artery disease by propping open a narrowed or blocked artery and releasing the drug, everolimus, in a controlled manner to prevent the artery from becoming blocked again following a stent procedure. Coronary artery disease occurs when plaque build-up narrows the arteries and reduces blood flow to the heart, which can lead to chest pain or a heart attack.

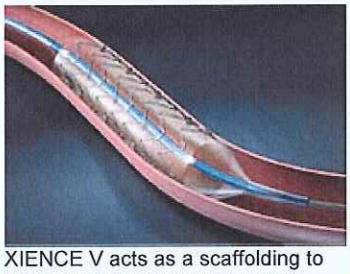
"XIENCE V was designed to improve safety and efficacy compared to earlier generation stents. The long-term clinical data from two studies performed in both the United States and Europe have now confirmed that XIENCE V is a true next-generation drug eluting stent with clinically important benefits for patients," said Gregg W. Stone, M.D., Columbia University Medical Center; chairman, Cardiovascular Research Foundation, New York; and principal investigator of the SPIRIT III U.S. pivotal clinical trial for XIENCE V.

Learn more about the XIENCE V Drug Eluting Stent in this Abbott animation.

- Windows Media
- QuickTime



During a stent procedure, a stent such as XIENCE V is placed over a small balloon. A doctor then uses a catheter to guide the balloon and stent through the femoral artery to the narrowed or blocked section of the coronary artery.



XIENCE V acts as a scaffolding to prop open clogged arteries and releases the drug everolimus in a controlled fashion to prevent the artery from becoming narrowed again.

Clinical Data Supporting XIENCE V

The robust clinical program for XIENCE V includes long-term data from a total of 1,362 patients enrolled in the SPIRIT FIRST, SPIRIT II and SPIRIT III trials, as well as continued access and post-approval programs that will enroll more than 14,000 XIENCE V patients.

The FDA approved XIENCE V based, in large part, on superior results from the 1,002 patient SPIRIT III U.S. pivotal clinical trial, in which XIENCE V demonstrated statistical superiority to TAXUS on the study's primary endpoint of in-segment late loss (vessel renarrowing) at eight months, with a statistically significant 50 percent reduction (mean, 0.14 mm for XIENCE V vs. 0.28 mm for TAXUS). XIENCE V also demonstrated statistical non-inferiority to TAXUS in the co-primary endpoint of target vessel failure (TVF, cardiac events related to the stented vessel) at nine months, with an observed 20 percent reduction (7.2 percent for XIENCE V vs. 9.0 percent for TAXUS). TVF is a composite clinical measure of safety and efficacy outcomes defined as cardiac death, heart attack (myocardial infarction or MI) or target vessel revascularization (TVR).

In May 2008, Abbott presented two-year data from the SPIRIT III trial demonstrating that XIENCE V continues to deliver positive clinical benefits for patients. At two years, the XIENCE V demonstrated the following key

results:

- A 45 percent reduction in the risk of major adverse cardiac events (MACE) compared to TAXUS (7.3 percent for XIENCE V vs. 12.8 percent for TAXUS, p-value=0.004)*. MACE is an important composite clinical measure of safety and efficacy outcomes for patients, defined as cardiac death, heart attack (MI) or ischemia-driven target lesion revascularization (TLR, repeat procedures driven by lack of blood supply).
- A 32 percent reduction in the risk of TVF compared to TAXUS (10.7 percent for XIENCE V vs. 15.4 percent for TAXUS, p-value=0.04)*.
- Low rates of stent thrombosis between one and two years, defined as very late stent thrombosis, per Academic Research Consortium (ARC) definition of definite/probable stent thrombosis (0.3 percent for XIENCE V and 1.0 percent for TAXUS) and per the SPIRIT III protocol (0.2 percent for XIENCE V and 1.0 percent for TAXUS). The ARC definition of late stent thrombosis was developed to eliminate variability in the definitions across various drug eluting stent trials.

* Event rates are based on Kaplan-Meier estimates; p-values are for descriptive purposes only.

"Today's approval of XIENCE V is a reflection of Abbott's ongoing commitment to bring innovation-driven, leading-edge medical technologies to the people who need them," added Capek. "With one of the largest, most seasoned vascular sales forces in the United States and with the ability to supply more than half the worldwide market, we will begin shipping units of XIENCE V immediately to meet physician demand for this much awaited, next-generation technology."

More About XIENCE V

XIENCE V is built upon Abbott's market-leading bare metal stent, the MULTI-LINK VISION® Coronary Stent System. The VISION platform is designed to facilitate ease of delivery, making it easier for physicians to maneuver the stent and treat the diseased portion of the artery.

The XIENCE V drug coated stent will be available on both over-the-wire (OTW) and rapid exchange (RX) delivery systems. Rapid exchange is the most widely used type of delivery system because it provides physicians additional flexibility to work as single operators during stent procedures.

XIENCE V was launched in Europe and other international markets in October 2006. XIENCE V is an investigational device in Japan and is currently under review for approval by Japan's Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA).

Abbott also supplies a private-label version of XIENCE V to Boston Scientific called the PROMUS™ Everolimus-Eluting Coronary Stent System. PROMUS is designed and manufactured by Abbott and supplied to Boston Scientific as part of a distribution agreement between the two companies.

Everolimus, developed by Novartis Pharma AG, is a proliferation signal inhibitor, or mTOR inhibitor, licensed to Abbott by Novartis for use on its drug eluting stents. Everolimus has been shown to inhibit in-stent neointimal growth in the coronary vessels following stent implantation, due to its antiproliferative properties.

Additional information about XIENCE V, including important safety and effectiveness information, is available online at www.xiencev.com.

About Abbott Vascular

Abbott Vascular, a division of Abbott, is one of the world's leading vascular care businesses. Abbott Vascular is uniquely focused on advancing the treatment of vascular disease and improving patient care by combining the latest medical device innovations with world-class pharmaceuticals, investing in research and development and advancing medicine through training and education. Headquartered in Northern California, Abbott Vascular offers a comprehensive portfolio of vessel closure, endovascular and coronary products.

About Abbott

Abbott (NYSE: ABT) is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs more than 68,000 people and markets its products in more than 130 countries.

Editor's Note:
Additional background information, including broadcast-quality video, animation and images, are available to members of the media through the XIENCE V media kit at www.xiencemediakit.com.

Media:
Kelly Morrison (847) 937-3802
Jonathon Hamilton (408) 390-5074

Financial:
John Thomas (847) 938-2655
Larry Peepo (847) 935-6722

top of page